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MEDICARE'S NEW PRESCRIPTION DRUG COVERAGE: A MAJOR STEP FORWARD, BUT BIG PROBLEMS STILL EXIST

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UNITED STATES SENATE

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FOREWORD

Prescription drugs are essential to maintaining quality of care and life itself for millions of older Americans. Prescribed inappropriately, however, some drugs can be as dangerous as a lethal poison.

Recognizing that far too many elderly for too long a time have gone without their medications for lack of money, the Congress enacted the Medicare Catastrophic Coverage Act of 1988. This Act is by no means the final solution to the high cost of drugs, but it is an important beginning. The Act also provides for safeguards against adverse drug reactions which may be caused by inappropriate prescribing.

This report serves as a guide to Medicare's forthcoming outpatient prescription drug coverage. The new benefit will be phased in over a 4-year period beginning in 1990. Also explained are the dangers of inappropriate prescribing, as well as steps taken by Congress to help ensure appropriate prescribing of drugs.

The Special Committee on Aging is hopeful that beneficiaries as well as their family members, physicians, pharmacists and social workers will find this paper helpful in understanding Medicare's new outpatient prescription drug benefit.

JOHN MELCHER,
Chairman.

JOHN HEINZ,
Ranking Minority Member.

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INTRODUCTION

When Medicare was signed into law by President Johnson in 1965, the new Federal health plan for the elderly was hailed as one of the most important social breakthroughs of the 20th century. At long last, all of the Nation's millions of elderly would have access to insurance protection against the costs of needed medical care.

For more than two decades, Medicare has provided older Americans with access to affordable, quality hospital care and physician services. But at the same time, the program grew unwieldy with regulations and conditions that confused beneficiaries, physicians and private insurers alike. Moreover, the confusing hospitalization benefit did not protect beneficiaries from the catastrophic costs associated with an unusually long stay in the hospital.

To cut through that bureaucratic maze, Congress passed and the President signed into law a new Medicare law, the Medicare Catastrophic Coverage Act of 1988, that included the most sweeping changes in the history of the program. Gone were many of the prerequisites and conditions that confused so many. Simplified were the rules. And, for millions of Americans, added was an important new provision to help beneficiaries pay for their prescription drugs.

The prescription drug coverage provided under the Medicare Catastrophic Coverage Act, along with the other improvements contained in the Act, represent the most important improvement to the program since eligibility was extended to the permanently disabled in 1973.

This report is the culmination of a year-long Aging Committee inquiry, including three hearings, into the use of prescription drugs by the elderly. The report should be of particular interest to older Americans, their families and advocates, physicians, nurses, pharmacists, dentists, state and local social service agencies,

insurers and policymakers. It outlines and defines three key issues:

(1) Medicare's limited coverage of outpatient prescription drugs;

(2) The critical need to establish an effective program for quality assurance in utilization of prescription drugs; and

(3) The role of the Food and Drug Administration in ensuring safety and effectiveness of drugs in the elderly.

Testimony at the committee's first two hearings clearly showed that millions of older Americans are finding it increasingly difficult to afford life-sustaining drugs. In too many instances, due to the burden of prescription drug costs, the elderly must choose between food and medicine.

The final hearing, conducted by Chairman Melcher on March 25, 1988, in Washington, D.C., looked at adverse drug reactions among the elderly and the adequacy of existing safeguards. Witnesses graphically illustrated how elderly face serious health risks from adverse drug reactions and interactions caused by excessive and inappropriate prescriptions.

These hearings provided some of the basis for including prescription drug coverage in the Medicare Catastrophic Coverage Act of 1988. The act provides a phased-in coverage of all outpatient prescription drugs approved by the FDS beginning in January 1991. The drug coverage provisions also include a requirement for the Department of Health and Human Services to establish a program to identify and correct drug utilization and quality problems.

If implemented properly, the review of drug utilization could save Medicare and its beneficiaries tens of millions of dollars a year by substantially reducing inappropriate prescribing. More importantly, reducing inappropriate prescribing will help protect elderly outpatients from adverse drug reactions and interactions which can result in serious illness requiring hospitalization or even death.

The Aging Committee's investigation also determined that FDA needs to strengthen its requirements for prescription drug labels. FDA-approved drug labels provide crucial information to health care providers on dosage and potentially harmful drug reactions and interac-

tions. But most of those same labels have little dosage and reaction information pertaining to elderly consumers. The committee also found that FDA has delayed for several years its guidelines for clinical testing of new drugs in the elderly.

Section I

THE HIGH COST OF DRUGS

Many elderly citizens find themselves caught in a dilemma when it comes to paying for their prescription drugs.

As drug costs rise, the elderly are forced to spend larger and larger amounts of their fixed incomes to pay for their medications, and less on food, housing, clothing and other necessities. Finding themselves in this financial squeeze, some elders have deviated from their prescribed drug regimens and, at great risk to their health, they either stop taking their medications, or take them less often in order to "stretch out" their supplies.

The Elderly and Their Drug Costs

Testimony received by the Committee at its hearing on July 20, 1987, supported the belief that the rising cost of prescription drugs has become unbearable for hundreds of thousands of older Americans. The lack of Medicare coverage of outpatient prescription drugs and partial coverage offered by many state Medicaid programs have resulted in an unacceptable financial hardship for hundreds of thousands, perhaps millions, of elders.

Older persons consume a disproportionately large percentage of prescription drugs. Although the elderly represent only 12 percent of the population, they consume 32 percent of all medications.[1] Applying this percentage figure to the number of prescriptions written in 1986, more than 480 million prescriptions were written that year for the elderly.[2] On average, the elderly person receives more than twice as many prescriptions as the person under 65.[3] Elderly living at home may consume two to four drugs daily, while one-third of the patients in nursing homes receive more than eight drugs daily.[4]

The Congressional Budget Office estimated that the average cost of a prescription in 1988 was $17.88, which helps to explain why as many as 36 percent of the elder-

ly may, at times, have problems purchasing their drugs.[5] One large Blue Cross and Blue Shield Plan reports that the average number of prescriptions filled for retirees in its private health plans was almost three times as high as the average number of prescriptions filled for all enrollees. The average prescription cost for retirees in that area was about 22 percent higher per retiree prescription than the average prescription cost for all enrollees.[6]

In 1985, expenditures for medications were the second highest out-of-pocket cost for the elderly. A 1986 study conducted by the American Association of Retired Persons (AARP) projected that 1986 drug costs for persons 65 and older will be $9 billion, with an estimated 81 percent or $7.3 billion coming as out-of-pocket costs.[7] Prescription drugs are the largest out-of-pocket health care expense for three of every four older Americans.[8] The lack of coverage for pharmaceuticals is surprising since drug therapy has been found to reduce the overall cost of health care.[9] According to a report by the U.S. Public Health Service, 15.5 percent of the elderly patients who require prescriptions said they are unable to pay for their drugs.[10]

Testimony before the Special Committee on Aging at its hearing on July 20, 1987 confirmed that the high cost of prescription drugs places a severe financial hardship on hundreds of thousands of this nation's elderly citizens. At the hearing, entitled "Prescription Drugs and the Elderly: The High Cost of Growing Old", several elderly Americans shared with the Committee their experiences in trying to cope with the devastating costs of prescription drugs.

Mrs. Faye Secrist, 61, testified that her 84-year-old mother, whose only income is her monthly $460 Social Security check, has a monthly drug bill of $264. After subtracting her mother's living expenses, including utility bills, insurance (life, fire, and health) and upkeep on her house, she is left with approximately $27 each month for food and clothing.[11]

Another witness, Mrs. Carrie Morris, 72, spoke of the cruel choices facing her each month due to the high costs of her medications. She receives $487 each month in income, but her monthly expenses total more than $400. Because of her costs, she said, "I have to decide on whether to buy medicine or food, because after all these

expenses, I have about . . . $30 a month." [12] During an interview with committee staff, Mrs. Morris said "Either I eat or I take my medicine. I want to do both, but I can't afford to." [13]

Mrs. Morris typifies those elderly who, for lack of money, do not take their expensive medications as directed in order to eat and pay the rent. Her physician had prescribed medication for regulating a faulty valve in Mrs. Morris' heart to ensure adequate flow of blood. Unable to fit the $1 per pill medicine in her meager budget, Mrs. Morris chose to "stretch out" her supply by not taking it as directed. Mrs. Morris testified that, although her doctor had ordered that she take the medicine every day, "I will have to wait until I have a pain [so] bad that I can't stand it before I can take the medicine." [14] When informed of Mrs. Morris's practice, her physician replied that not taking her medicine as prescribed is "a great risk to her health" and increases the possibility of a heart attack.[15]

Drug Prices Have Risen Faster Than Other Consumer Items

Prescription drug prices have risen steadily for the past several years, increasing at a faster rate than other items in the Consumer Price Index (CPI).[16] The Health Care Financing Administration reported a 300 percent increase in total spending for prescription drugs from 1965 to 1982.[17] Prior to 1981, prescription drug price increases had outpaced the consumer price index only once since 1967. From January 1980 through 1986, drug prices rose approximately 80 percent—250 percent faster than the increase in consumer prices in general.[18] In 1986, prescription drug prices remained the highest of all medical care components of the CPI, increasing at a rate of 8.6 percent.[19]

Another indicator of the increasing costs of prescription drugs is the growth in insurance benefits paid by insurers over the past several years. For example, in 1980, Blue Cross and Blue Shield of Michigan paid $120 million in drug benefits. By 1986, Blue Cross and Blue Shield of Michigan drug benefit payments had risen to $311 million. In 1 year alone, this private insurance carrier's prescription drug benefit payments increased by 21 percent, from $257 million in 1985 to $311 million in

1986. Blue Cross and Blue Shield of Michigan estimated that approximately half of its 1986 increase was due to increases in drug prices.[20]

Medicare, Medicaid, and Private Insurance Provide Limited Coverage

Mrs. Cleo Lovell, a witness at the July 20, 1987, Aging Committee hearing, described the problems she encountered because her mother, Mrs. Ollie Bratten, had extremely high drug bills, and her insurance company would not pay. Mrs. Bratten took 36 medications during the last 2 years of her life and, at the time of her death in May of 1987, she was taking 12 medications simultaneously. The costs for her drugs were enormous, about $4,000 over the last 2 years. Mrs. Lovell testified that, contrary to her expectations, her mother's insurance carrier did not pay for her drug costs. Mrs. Lovell further stated: "Blue Cross sent us a letter saying that they would help my mother on her medicine. Six months later I heard from the drug store that Blue Cross would not pay it . . ." I never got any help from Blue Cross on her medicine. I never got any help from anyone." [21]

Unfortunately, Mrs. Lovell's situation is not unique. The lack of insurance coverage (Medicare or private policies) for assistance with prescription drug costs has worked an additional financial hardship on those elderly persons who live on small fixed retirement incomes.

Until Medicare's limited and phased-in coverage of outpatient prescription drugs begins on January 1, 1991, the elderly must continue largely to fend for themselves. According to surveys conducted in 1985 and 1986 by the American Association of Retired Persons (AARP), 55 percent of the Nation's elderly received no insurance or other assistance in paying for their medicines. Further, 71 percent of those over 65 who received assistance for their drug bills still had to pay for some out-of-pocket costs.[22] While 75 percent of those persons between the ages of 19 and 64 have insurance coverage for prescription drugs, only 41 percent of those 65 and over have coverage.[23] The 1986 AARP survey supported this lack of coverage and showed that older consumers cite the costs of drugs as the second most important reason for not getting a prescription filled.[24]

Prescription Drug Coverage Under Medicaid

The elderly poor on Medicaid receive some prescription drug benefits in most States. According to the Health Care Financing Administration, 2.3 million Medicare beneficiaries also are covered by State Medicaid programs.[25] Two States, Wyoming and Alaska, offer no Medicaid drug benefit.[26] The chart on the following page indicates that only three States, Montana, North Dakota and Texas, place no restrictions on Medicaid drug coverage. Other State Medicaid programs contain restrictions such as exclusion of certain drugs, restricting drugs to a specific illness and limiting coverage to a maximum number of drugs prescribed each month. Medicaid drug coverage in 22 States require the patient to pay part of the cost of each prescription through "copayments" ranging from 50 cents to $3 per prescription.[27]

Because of different State eligibility rules and lack of knowledge of the limits of coverage, only 36 percent of the noninstitutionalized elderly poor were enrolled in Medicaid in 1984.[28] Medicaid eligibility is means-tested and was designed to assist only the poorest of the elderly. Consequently, there are millions of elderly Americans whose incomes are just above Medicaid eligibility levels and therefore are denied assistance.[29]

Appendix I

State Medicaid Coverage

State	Copayment	Formulary	Restrictions		
			Excludes drugs	Restricts drugs to specific illness	Other major restrictions
Alabama	$0.50-$3.00	yes		yes	
Alaska	No drug program	[a]			
Arizona	[b]	[a]			
Arkansas	0	no	yes		4 Rx/month
California	$1.00 (optional)	yes		yes	
Colorado	$0.50	no	yes		
Connecticut	0	no	yes		
Delaware	0	no	yes		
District of Columbia	$0.50	no	yes		
Florida	0	no	yes		$22/month
Georgia	0	yes		yes	6 Rx/month
Hawaii	0	yes		yes	
Idaho	0	no	yes		
Illinois	0	yes		yes	
Indiana	0	no	yes		
Iowa	$1.00	no	yes		
Kansas	$1.00	yes		yes	
Kentucky	0	yes		yes	
Louisiana	0	no	yes		
Maine	$0.50	no	yes		
Maryland	$0.50 (for state funded)	no	yes		
Massachusetts	0	no	yes		
Michigan	$0.50	yes		yes	
Minnesota	0	yes		yes	
Mississippi	$1.00	yes		yes	4 Rx/month
Missouri	$0.50-$2.00	yes		yes	5 Rx/month
Montana	$0.50	no			
Nebraska	0	no	yes		

State	Copayment	Formulary	Restrictions		
			Excludes drugs	Restricts drugs to specific illness	Other major restrictions
Nevada	$1.00	no	yes		3 Rx/month
New Hampshire	$0.75	no	yes		
New Jersey	0	no	yes		
New Mexico	0	no	yes		
New York	0	yes		yes	
North Carolina	$0.50	no			6 Rx/month
North Dakota	0	no			
Ohio	0	yes		yes	
Oklahoma	0	yes		yes	3 Rx/month
Oregon	0	no	yes		
Pennsylvania	$0.50	no	yes		
Rhode Island	0	yes		yes	
South Carolina	$0.50	no	yes		3 Rx/month
South Dakota	$1.00	yes		yes	
Tennessee	0	yes		yes	7 Rx/month
Texas	0	no			
Utah	0	no	yes		
Vermont	$1.00	no	yes		
Virginia	$0.50-$1.00	no	yes		
Washington	0	yes		yes	
West Virginia	$0.50-$1.00	yes		yes	
Wisconsin	$0.50	no	yes		
Wyoming	No drug program	[a]			

[a]Not applicable

[b]There is no copayment, depending on a formula under an Arizona Health Care Cost Containment System capitation plan

Source: Joseph A. Cislowski, "Coverage of Outpatient Prescription Drugs," report for the Senate Finance Committee, Congressional Research Service, Washington, D.C., June 15, 1987

Coverage Under State Programs

In addition to Medicaid drug coverage, nine States have programs that provide limited coverage of prescription drugs for portions of their elderly populations. A majority of the elderly in these States, however, are excluded from the benefit because of means-testing.[30] For example, in Connecticut, individuals receiving more than $13,300 and couples receiving more than $16,000 cannot participate in the program. Consequently, thousands of the near poor do not receive benefits from these programs. According to the General Accounting Office, the percentage of the elderly population in these nine States receiving benefits range from only 4 percent to 27 percent.

Private Insurance Coverage of Prescription Drug Costs

A number of private insurance companies sell Medicare supplemental "medigap" policies which cover some or all the costs of prescription drugs. However, because Medicare currently does not cover any of the costs of outpatient prescription drugs and because the increasing costs of these drugs pushes up the liability and the costs of these medigap policies, most insurers have hesitated to include such coverage in the majority of their policies. Furthermore, those policies that do offer substantive coverage are often too expensive for many Medicare beneficiaries to afford. As a result, the majority of older Americans do not have a medigap policy which offers protection against the costs of prescription drugs.

As section II of this report will describe, however, the newly enacted catastrophic health care law provides for a limited Medicare prescription drug benefit. This benefit will be phased in over a 4-year period beginning in 1990. As a result, a number of medigap policies are expected to build onto the new Medicare catastrophic prescription drug benefit and offer protection against drug costs not covered under this new law.

It is important to note, however, that private insurance companies will not be required to offer in their policies supplemental coverage of outpatient prescription drugs in order to sell their policies as medigap policies. According to the minimum medigap insurance standards (adopted by the National Association of Insur-

ance Commissioners in September 1988 and expected to be adopted by most States), a supplemental insurance policy may be labeled and sold as a medigap policy as long as it pays for the required copayments for Medicare-covered immunosuppressive medications and intravenous drugs administered in the home.[31] In other words, while medigap policies may cover the costs of the new Medicare prescription drug deductible and copayments (except for the immunosuppressives and administered-in-the-home intravenous drugs), they will not be required to do so.

As a result, should a Medicare beneficiary wish to purchase significant drug coverage, he or she will have to closely evaluate how each policy matches up with the new Medicare coverage. Section II of this report explains the new Medicare benefit and should help in this regard.

Medicare's Outpatient Prescription Drug Coverage

Outpatient prescription drug coverage under Medicare has been a long time in the making. Prior to passage of the Medicare Catastrophic Coverage Act of 1988, the Congress had debated the issue of outpatient drug coverage since 1969. Budget constraints largely were responsible for delays in passage of Medicare outpatient drug coverage.

Medicare's new prescription drug benefit for outpatients will be phased in over a 4-year period, beginning in January 1990. As a result, those elderly who are not eligible for Medicaid and who do not have private insurance coverage for prescription drugs will continue to have out-of-pocket drug expenses even after the phase-in of Medicare coverage is completed in 1993.

Details of Medicare's limited, phased-in outpatient prescription drug benefit are discussed in section II of this report.

Section II

MEDICARE'S COVERAGE OF OUTPATIENT PRESCRIPTION DRUGS

Medicare's limited outpatient prescription drug coverage, catastrophic drug insurance, will not begin until 1990 and will be phased in gradually over a four-year period.

Eligibility is based on the following requirements:

The beneficiary must be a subscriber of Part B of Medicare, which provides for outpatient (out-of-hospital) medical services;

The beneficiary must be residing outside of the hospital, at home or in a nursing home where the recipient is not receiving skilled nursing care, when the medication is prescribed;

The beneficiary must meet the prescription drug benefit's deductible (either out of his or her own pocket, with a private "medigap" insurance policy that covers this deductible or, if eligible, through his or her state's Medicaid program). The outpatient drug coverage deductible is separate from Medicare's hospital deductible.

The medication has been prescribed by a physician and it is not an over-the-counter drug.

The following is a year-by-year summary of how the new Medicare catastrophic drug insurance benefit will be phased in:

1990: First Year of Phased-In Benefit

COVERAGE

Beginning on January 1, 1990, the new prescription drug benefit will cover only intravenous medications administered in the beneficiary's home and immunosuppressive therapy drugs during the first year following a Medicare-covered organ transplant. All other outpatient prescription drug costs incurred during the year must be paid for by the beneficiary, his or her private supple-

mental medigap policy (if it covers prescription drugs) or, if the beneficiary qualifies, his or her State's Medicaid program.

DEDUCTIBLE

The Medicare outpatient will be required to pay a $550 deductible during calendar year 1990 before Medicare begins paying 80 percent of the prescription costs. However, the beneficiary is exempt from paying the deductible for immunosuppressive drugs during the first year after an organ transplant and intravenous drugs administered in the home if they are prescribed in the hospital before the beneficiary is discharged and returns home.

COPAYMENT

Once the beneficiary has met the $550 deductible for 1990, he or she is responsible for 20 percent of the cost (either out of his or her own pocket, with his or her medigap policy or, if eligible, through his or her State's Medicaid program) of intravenous drugs prescribed in 1990 and every year thereafter. In the case of immunosuppressive drugs, the patient will be responsible for 20 percent of the costs during the first year following a Medicare-covered organ transplant and 50 percent of the costs every year thereafter.

1991: Second Year of Phased-In Benefit

COVERAGE

Beginning on January 1, 1991, *all* prescription drugs will be covered by the phased-in program.

DEDUCTIBLE

During 1991, the beneficiary is responsible for the first $600 of prescription drug costs before Medicare begins to pay 50 percent of prescription costs. This deductible applies to all prescriptions, except for immunosuppressive drugs prescribed during the first year following a Medicare-covered organ transplant and intravenous medications administered in the beneficiary's home following hospitalization.

COPAYMENT

After paying the first $600 of outpatient prescription drug costs, the beneficiary will be responsible for paying 50 percent of the cost of all Medicare-covered prescription drugs (either out of his or her own pocket, with his or her medigap policy or, if eligible, through his or her State's Medicaid program). This copayment applies to all prescription drugs, except for immunosuppressive drugs prescribed during the first year following a Medicare-covered organ transplant and intravenous medications administered in the outpatient's home following hospitalization.

1992: Third Year of Phased-In Benefit

COVERAGE

During the third year of coverage, the phase-in continues with an increase in the deductible and a decrease in the beneficiary's copayment.

DEDUCTIBLE

During 1992, the Medicare outpatient must pay an estimated deductible of $652 for outpatient prescription drugs before Medicare begins to pay for 60 percent of prescription costs. This deductible applies to all prescription drugs, except for immunosuppressive drugs prescribed during the first year following a Medicare-covered organ transplant and intravenous medications administered in the outpatient's home following hospitalization.

COPAYMENT

Once the beneficiary meets the estimated $652 prescription drug deductible for 1992, Medicare will cover 60 percent of prescription drug costs. The beneficiary will be required to pay a 40 percent copayment (either out of his or her own pocket, with his or her medigap policy or, if eligible, through his or her State's Medicaid program). This copayment applies to all prescription drugs, except for immunosuppressive drugs prescribed during the first year following a Medicare-covered organ transplant and intravenous medications administered in the beneficiary's home following hospitalization.

1993 AND BEYOND

COVERAGE

The phase-in of coverage is completed in 1993, with Medicare's coverage of outpatient prescription drug costs rising to 80 percent after the beneficiary pays a deductible estimated to be more than $700. The deductible likely will increase in every year thereafter, to be set at a level to assure that approximately 17 percent of Medicare beneficiaries will receive the catastrophic outpatient drug benefit.

DEDUCTIBLE

In 1993 and beyond, the Medicare beneficiary will be responsible for paying the annual outpatient prescription drug deductible before Medicare begins to pay for 80 percent of prescription costs. This deductible applies to all prescription drugs, except for immunosuppressive drugs during the first year following a Medicare-covered organ transplant and intravenous medications administered in the beneficiary's home following hospitalization.

COPAYMENT

After paying the deductible, the beneficiary will be eligible for Medicare coverage of prescription drug costs and will be required to pay a 20 percent copayment for all outpatient prescription drugs in 1993 and every year thereafter (either out of his or her own pocket, with his or her medigap policy or, if eligible, through his or her state's Medicaid program).

THE MEDICARE OUTPATIENT'S SHARE OF PRESCRIPTION COSTS

Until 1993, the fourth year of the phase-in period, the Medicare outpatient's share of prescription costs will continue to be substantial, especially for the elderly on small fixed incomes. During 1990, the first year of coverage, the Medicare beneficiary will continue to absorb all outpatient prescription drug costs—other than for intravenous drugs administered in the home following hospitalization and immunosuppressive drugs taken during the first year after a Medicare-covered organ transplant.

The following examples of coverage exclude intravenous drugs administered in the home following hospitalization and immunosuppressive medications prescribed during the first year following a Medicare-covered organ transplant:

In *1990,* if a beneficiary spends a total of $1,000 on outpatient prescription drugs, Medicare will pay for none of it.

In *1991,* if a beneficiary spends $1,000 on outpatient drugs, he or she will be responsible for $800 of the costs, the $600 deductible and half ($200) of the remaining $400. Medicare will pay for the other $200.

In *1992,* a beneficiary with a $1,000 prescription drug bill will be responsible for $791 of the costs, including the $652 deductible and 40 percent ($139) of the remaining $348. Medicare will cover the other $209.

In *1993,* the deductible is expected to increase, but the beneficiary's copayment will drop to 20 percent. If, for example the deductible for that year is set at $700 and the beneficiary's outpatient drug expenses totaled $1,000, he or she would be responsible for $760 of the costs. Medicare would pay the remaining $240.

For *1994 and years beyond,* the beneficiary's copayment will remain at 20 percent, with continuing Medicare coverage of 80 percent of outpatient prescription drug costs. The deductible, however, is expected to increase yearly.

Tables on the following pages provide easy-to-follow information on the phase-in of Medicare's Catastrophic Drug Insurance program.

1990: First Year Of Phased-In Coverage

IMMUNOSUPPRESSIVE DRUGS

You Pay	Medicare Pays
Deductible:	
NONE during the first year that the drug is prescribed following an organ transplant.	
$550 if the drug is being prescribed beyond the first year following an organ transplant.	
Copayment:	Coverage:
20% of the drug costs during the first year that the drug is prescribed following an organ transplant.	80% of the drug costs during the first year that the drug is prescribed following an organ transplant.
50% of the drug costs if the drug is being prescribed beyond the first year following an organ transplant.	50% of the drug costs if the drug is being prescribed beyond the first year following an organ transplant.

1990: First Year Of Phased-In Coverage

INTRAVENOUS DRUGS
(administered in the home)

You Pay	Medicare Pays
Deductible:	
NONE if the drug is administered in the home following a hospitalization.	
$550 if administration of the drug in the home does not follow a hospitalization.	
Copayment:	Coverage:
(If there is no deductible) 20% of all drug costs.	(If there is no deductible) 80% of all drug costs.
(If there is a deductible) 20% of drug costs over the deductible.	(If there is a deductible) 80% of drug costs over the deductible.

1990: First Year Of Phased-In Coverage

ALL OTHER PRESCRIPTION DRUGS	
You Pay	Medicare Pays
NO MEDICARE COVERAGE IN 1990	
(MEDICARE BENEFICIARY PAYS ALL COSTS FOR THESE DRUGS.)	

1991: Second Year Of Phased-In Coverage

IMMUNOSUPPRESSIVE DRUGS

You Pay	Medicare Pays
Deductible:	
NONE during the first year that the drug is prescribed following an organ transplant.	
$600 if the drug is being prescribed beyond the first year following an organ transplant.	
Copayment:	Coverage:
20% of the drug costs during the first year that the drug is prescribed following an organ transplant.	80% of the drug costs during the first year that the drug is prescribed following an organ transplant.
50% of the drug costs if the drug is being prescribed beyond the first year following an organ transplant.	50% of the drug costs if the drug is being prescribed beyond the first year following an organ transplant.

1991: Second Year Of Phased-In Coverage

INTRAVENOUS DRUGS
(administered in the home)

You Pay	Medicare Pays
Deductible:	
NONE if the drug is administered in the home following a hospitalization.	
$600 if administration of the drug in the home does not follow a hospitalization.	
Copayment:	Coverage:
(If there is no deductible) 20% of all drug costs.	(If there is no deductible) 80% of all drug costs.
(If there is a deductible) 20% of drug costs over the deductible.	(If there is a deductible) 80% of drug costs over the deductible.

1991: Second Year Of Phased-In Coverage

ALL OTHER PRESCRIPTION DRUGS

You Pay	Medicare Pays
Deductible: $600	
Copayment: 50% of the drug costs over the deductible.	Coverage: 50% of the drug costs after the deductible has been paid by the beneficiary.

1992: Third Year Of Phased-In Coverage

IMMUNOSUPPRESSIVE DRUGS

You Pay	Medicare Pays
Deductible:	
NONE during the first year that the drug is prescribed following an organ transplant.	
$652 if the drug is being prescribed beyond the first year following an organ transplant.	
Copayment:	Coverage:
20% of the drug costs during the first year that the drug is prescribed following an organ transplant.	80% of the drug costs during the first year that the drug is prescribed following an organ transplant.
40% of the drug costs if the drug is being prescribed beyond the first year following an organ transplant.	60% of the drug costs if the drug is being prescribed beyond the first year following an organ transplant.

1992: Third Year Of Phased-In Coverage

INTRAVENOUS DRUGS
(administered in the home)

You Pay	Medicare Pays
Deductible:	
NONE if the drug is administered in the home following a hospitalization.	
$652 if administration of the drug in the home does not follow a hospitalization.	
Copayment:	Coverage:
(If there is no deductible) 20% of all drug costs.	(If there is no deductible) 80% of all drug costs.
(If there is a deductible) 20% of drug costs over the deductible.	(If there is a deductible) 80% of drug costs over the deductible.

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1992: Third Year Of Phased-In Coverage

ALL OTHER PRESCRIPTION DRUGS

You Pay	Medicare Pays
Deductible:	
$652	
Copayment:	Coverage:
40% of the drug costs over the deductible.	60% of the drug costs after the deductible has been paid by the beneficiary.

1993: Fourth Year Of Phased-In Coverage
(And Every Year Thereafter)

IMMUNOSUPPRESSIVE DRUGS	
You Pay	Medicare Pays
Deductible:	
NONE during the first year that the drug is prescribed following an organ transplant.	
(TO BE DETERMINED) The deductible must be paid if the drug is prescribed beyond the first year following an organ transplant.	
Copayment:	Coverage:
20% of the drug costs during the first year that the drug is prescribed following an organ transplant.	80% of the drug costs during the first year that the drug is prescribed following an organ transplant.
20% of the drug costs if the drug is being prescribed beyond the first year following an organ transplant.	60% of the drug costs if the drug is being prescribed beyond the first year following an organ transplant.

1993: Fourth Year Of Phased-In Coverage
(And Every Year Thereafter)

INTRAVENOUS DRUGS
(administered in the home)

You Pay	Medicare Pays
Deductible:	
NONE if the drug is administered in the home following a hospitalization.	
(TO BE DETERMINED) The deductible must be paid if administration of drug in the home does not follow a hospitalization.	
Copayment:	Coverage:
(If there is no deductible) 20% of all drug costs.	(If there is no deductible) 80% of all drug costs.
(If there is a deductible) 20% of drug costs over the deductible.	(If there is a deductible) 80% of drug costs over the deductible.

1993: Fourth Year Of Phased-In Coverage
(And Every Year Thereafter)

ALL OTHER PRESCRIPTION DRUGS	
You Pay	Medicare Pays
Deductible: (TO BE DETERMINED)	
Copayment: 20% of the drug costs over the deductible.	Coverage: 80% of the drug costs after the deductible has been paid by the beneficiary.

Important Notice

The prescription drug deductible outlined in the preceding charts need not be met by your own personal out-of-pocket payments. The deductible is based on "incurred" costs. This means that if you have a "medigap" supplemental insurance policy that covers any or all of Medicare's prescription drug deductible, or if your State's Medicaid program pays these costs for you, those payments will count toward your deductible as if you paid them out of your own pocket.

Section III

DANGERS AND COSTS OF INAPPROPRIATE PRESCRIBING

In addition to providing limited, phased-in coverage of outpatient drugs, the Medicare Catastrophic Coverage Act of 1988 addresses the problem of inappropriate and sometimes dangerous prescribing.

How often are drugs inappropriately prescribed by Physicians? No one knows, primarily because sufficient accurate data are not available. Nonetheless, available research findings indicate that the problem is significant, especially for the elderly, and results in waste of tens, perhaps hundreds, of millions of dollars annually. More importantly, inappropriate prescribing can, and too often does, exact a far heavier cost in terms of human suffering and even death.

Evidence of Inappropriate Prescribing

Simply defined, an inappropriate prescription is one that is either unnecessary or capable of causing a potentially serious adverse reaction, or both.

Government-sponsored and university-based studies provide ample evidence of drug prescribing that is both unnecessary and sometimes dangerous. Further, these studies indicate that elderly individuals are more likely to fall victim to inappropriate prescribing, simply because elderly are likely to suffer from multiple chronic and acute illnesses requiring multiple prescriptions.

For example, a 1983 study of elderly nursing home residents determined that two-thirds of the patients who were taking the maintenance drug digitalis [32] did not need this therapy.[33]

Studies conducted in 1980 [34] and 1986 [35] by researchers at the Vanderbilt University School of Medicine clearly indicate inappropriate and excessive prescribing of psychotropic drugs [36], especially powerful antipsychotics, in some Tennessee nursing homes. The 1986 study revealed sharp differences between prescrip-

tions for elderly outpatients and nursing home residents, 65 and older, in Tennessee.[37] Twenty-five percent of the 82,060 duly eligible Medicaid/Medicare enrollees studied during a 1-year period resided in nursing homes. The study utilized the state of Tennessee's Medicaid Management Information System, a computerized record of drug prescriptions and other health services covered by Medicaid. Results showed that psychotropic drugs (minor tranquilizers, antipsychotics, antidepressants, and hypnotics) were prescribed twice as often for elderly residing in nursing homes than for those living in the community. In fact, psychotropics were the second most frequently prescribed class of drugs for elderly in nursing homes. Moreover, almost 40 percent of the nursing home residents between 65 and 84 were prescribed powerful and potentially dangerous antipsychotic drugs primarily used for treatment of schizophrenia in younger individuals.[38] For those living in the community, however, only 5 percent of the elderly were prescribed these powerful tranquilizers.[39]

An earlier study, conducted in 1980 by the same Vanderbilt researchers, focused on the prescribing of antipsychotics during 1 year for elderly patients in 173 Tennessee nursing homes (facilities specializing in psychiatric care were excluded). The findings indicate that, in the case of antipsychotics, a small minority of physicians prescribed inappropriately and excessively resulting in serious misuse of these incapacitating tranquilizers in some nursing homes. Over 44 percent (2,600) of the 5,902 nursing home patients received a total of more than 700,000 daily doses of antipsychotic drugs during the study year.[40] According to researchers, 549 (9.3 percent) of these patients were long-term recipients of powerful tranquilizers.[41] One patient was prescribed more than 3,600 daily doses (almost 10 doses per day) during the 12-month period.

The second study showed that, of the 1,580 physicians who prescribed a variety of drugs for the nursing home patients, 666 (42 percent) prescribed antipsychotic medications.[42] The study revealed that 1.3 percent of the physicians (20) prescribed 37 percent of the antipsychotic drugs.[43] One physician alone prescribed 55,280 doses in 1 year for only 217 nursing home patients (255 doses per patient).[44] Research also revealed that physicians whose nursing home practice included 10 or more pa-

tients (14 percent) prescribed 81 percent of the daily doses of antipsychotic drugs.[45]

Findings in a more recent study by a private firm, Pharmaceutical Data Service, Inc. (PDS), confirm inappropriate and excessive prescribing of psychotropic drugs (powerful and mild tranquilizers, antidepressants and hypnotics) in nursing homes. The firm's database of approximately 7 million prescriptions dispensed by 2,000 pharmacies in 1986 showed that prescribing of psychotropic drugs for elderly nursing home residents is almost double that of nonnursing home elderly.[46] Moreover, while 60.5 percent of the psychotropic prescriptions for the nursing home elderly were for antipsychotics (powerful tranquilizers), only 12.5 percent of the psychotropic prescriptions for nonnursing home elderly were for the powerful tranquilizers.[47]

Even more startling was the PDS finding that haloperidol, a powerful and potentially dangerous tranquilizer, was the sixth most often prescribed drug for nursing home elderly, and thioridazine hydrochloride, also a major tranquilizer, was the seventh most often prescribed drug for the same population.[48] By comparison, in the nonnursing home elderly population, haloperidol was ranked 99th, and thioridazine hydrochloride, 90th.[49]

Why would elderly nursing home residents receive such disproportionate amounts of incapacitating tranquilizers compared to nonnursing home elderly? The answer often lies in the ratio of nursing home staff to the number of patients. The smaller the staff, the more likely patients will be subjected to chemical restraints, especially those patients who exhibit disruptive behavior and nocturnal restlessness.[50]

Additional evidence of inappropriate prescribing has been documented in other university research. In another Vanderbilt study, a researcher conducted an education intervention study involving instructive visits to physicians by other physicians and clinical pharmacists. These face-to-face visits resulted in an estimated 25 percent reduction in unnecessary prescriptions for expensive cephalosporin antibiotics.[51] The State Medicaid computerized database was used to identify frequent prescribers of these antibiotics.[52]

A similar study, a three-year project by a Harvard University researcher in three other states and the Dis-

trict of Columbia, reduced inappropriate prescribing of three prescription drug groups by 14 percent overall.[53] This study utilized the Medicaid Management Information Systems in each of the States (Arkansas, New Hampshire, and Vermont) and the District of Columbia to identify physicians who had prescribed these drugs up to certain levels.[54]

DEFINITION AND CAUSES OF INAPPROPRIATE PRESCRIBING

Inappropriate prescribing includes the following situations:

The physician fails to prescribe the correct dosage of a drug;

A prescription drug that will cause an adverse reaction in combination with another drug;

The physician prescribes a drug that is unnecessary;

A prescription that is wrong for the patient's condition(s);

The patient receives a prescription when he or she has a condition that will lead to an adverse reaction; and

A prescription that results in overdose or dependency.

What are the causes of inappropriate prescribing? The reasons can be attributed to the physician, the patient or both. The following situations can and often do lead to a wrong prescription:

The patient may intentionally or unintentionally fail to inform one physician that he or she is receiving prescriptions from one or more other physicians;

The physician may fail to question the patient about whether he or she is receiving prescriptions from other physicians;

The physician may not obtain complete information on the patient's medical condition which could affect the patient's response to the drug prescribed;

The patient may fail to inform the physician of allergic reactions to certain medications;

The physician may neglect to question the patient about allergic reactions to medications;

The physician may prescribe the wrong dosage; and

The physician is fully aware of the patient's condition, allergies and all of the patient's prescriptions, but mistakenly orders an unnecessary or potentially harmful prescription.

Physicians' Lack of Knowledge in Prescribing for the Elderly

A far more disturbing reason for inappropriate and excessive prescriptions may be a physician's lack of knowledge about prescribing for the elderly. Several studies support the need for more emphasis on geriatric pharmacology in medical schools and in continuing education programs for physicians. For example, a Temple University survey of physicians[55] in 1984 showed that "less than 30 percent of the participating physicians exhibited adequate knowledge of prescribing for the elderly." [56] The study further "suggest[ed] that many of these physicians had not had available to them, had not known there was available to them, or had not made good use of the best information on prescribing for the elderly." [57]

Results of a survey of pharmacists [58] conducted by Oregon State University researchers revealed:

> "Inadequate knowledge and skills in geriatric pharmacy was the most commonly cited difficulty in geriatric pharmacy";
>
> "Twenty-one percent of the pharmacists perceived significant deficits in physician functioning as the most difficult aspect of geriatric pharmacy practice"; and
>
> "Overprescribing of medications by physicians, 'psychotropic drugs to make the elderly manageable,' or prescribing for 'every symptom, including drug-induced reactions'." [59]

Unfortunately, many of the more than 300,000 office-based physicians obtain much, if not most, of their information on drug uses and effects from visiting drug company sales personnel and from advertisement labels written by the drug manufacturer and approved by the Food and Drug Administration (FDA). The Physicians' Desk Reference (PDR), an incomplete compendium of the FDA-approved labels, is the information source most widely used by physicians. The PDR contains the labels for only about one-fourth (2,500) of the more than

10,000 drug products on the market, simply because the PDR itself is an advertisement provided free of charge to physicians yearly. Moreover, while most of the FDA-approved advertisement labels contain specific dosage and adverse-effect warning sections for nursing mothers, infants, children and pregnancy, such a section seldom is included for use in the elderly.

There are several other published reference volumes that contain more complete information on use and effects of drug products in the elderly and, therefore, are far more useful and helpful to the physician as well as to the pharmacist.[60] However, these are not provided free of charge and cost over $100 a year for subscription. Few physicians subscribe to these reference volumes.

Inappropriate Prescribing Wastes Millions of Dollars Annually

A growing number of research studies clearly indicate that inappropriate prescribing of drugs results in unnecessary and wasteful expenditures by government and private insurance as well as by recipients of these prescriptions. Findings of these studies were largely responsible for inclusion of a provision for prescription drug "utilization and quality assurance" in the Medicare Catastrophic Coverage Act of 1988.

In 1986 alone, physicians in the U.S. wrote more than 1.5 billion prescriptions.[61] Approximately 480 million (32 percent) of those prescriptions were written for elderly patients[62] at a cost of more than $8.4 billion.[63] If one estimate that 25 percent of the drugs consumed by the elderly may be unnecessary or ineffective[64] is correct, this would mean that as many as 120 million prescriptions costing more than $2 billion were inappropriate.[65]

A dozen states[66] have established drug utilization review (DUR) programs in an effort to cut their Medicaid costs by retrospectively analyzing computerized information on prescription drugs paid for by Medicaid. These DUR programs share similar goals: to reduce unnecessary and expensive drug therapy and reduce inappropriate and excessive prescribing which can lead to drug-induced illness resulting in costly physician and

hospital services. Several of these States claim substantial savings.

In 1986, for example, the Michigan DUR program was credited for having reduced the number of Medicaid-covered hospitalizations by 798, an estimated savings of $2.65 million to Michigan's Medicaid program.[67] In that same year, Arkansas' DUR program reported significant savings on Medicaid expenditures for two widely used drug categories in the elderly. Arkansas realized a $292,452 savings from a reduction of 10,744 prescriptions for aspirin substitute pain relievers (Motrin, Naprosyn, Indocin, etc.), and about $109,000 from a reduction of 6,029 prescriptions (12 percent) for antidepressants (tricyclic/tetracyclic).[68] The Arkansas DUR program also claims to have saved more than $500,000 by reducing the number of hospitalizations caused by drug-induced illnesses.[69] Mississippi's DUR program saved its Medicaid program more than $1 million in 1985 and 1986,[70] and Nebraska reported saving more than $452,000 in 1985.[71]

These Medicaid drug utilization review programs, however, consist of retrospective computer analyses of prescriptions that have already been dispensed. While these analyses assist in identifying physicians who may be prescribing drugs that are unnecessary and harmful, the patient may already have suffered a severe adverse drug reaction or interaction between two or more drugs.

The Medicare Catastrophic Coverage Act of 1988 provides for a computerized information system to alert the pharmacist to certain potential problems associated with inappropriate prescribing before the prescription is filled. This new system, which must be installed in drugstores by January 1, 1991, is discussed in detail in section III of this report.

Dangers of Inappropriate Prescribing

In addition to enormous waste of Federal and State health care dollars as well as the limited resources of elderly on small fixed incomes, inappropriate prescribing often causes adverse drug reactions which can lead to drug-induced illness and hospitalization, and even death.

The primary causes of adverse drug reactions include: allergic reaction, interaction of two or more drugs, and

reaction to a drug brought on by an existing physical condition or illness. Adverse reactions range from such minor effects as dizziness, nausea and skin rash to such serious and life-threatening effects as anemia and heart attack. For example, if given at too high a dose, digoxin, a medication widely prescribed for heart conditions, can cause nausea, vomiting, blurred vision, confusion, delirium, hallucinations, coma and even heart attack.[72] Overdosing with antihypertensives, drugs used for controlling high blood pressure, can cause or exacerbate such conditions as headaches, depression, gout, Parkinson's disease and dementia.[73]

Elderly who are taking multiple drug prescriptions for multiple illnesses are especially vulnerable to adverse drug reactions.[74-75] Moreover, such reactions often are exaggerated and more serious in elderly because aging increases sensitivity to certain medications.

Frequency of Adverse Drug Reactions

To what extent are elderly consumers of prescription drugs experiencing adverse reactions? As in the case of inappropriate prescribing discussed earlier in this section, there currently is no way to quantify this problem.

The Food and Drug Administration (FDA) maintains a computer database on adverse reaction reports it receives from drug manufacturers and physicians and other health care providers. Reporting by physicians and other health care providers, however, is voluntary. Consequently, many, if not most, adverse reactions go unreported, especially those involving the elderly.[76]

Factors that are believed to discourage voluntary reporting include: fear of being sued, guilt, ignorance of the reporting mechanism, lack of interest, lack of certainty, and failure to make the connection between the drug(s) and the reaction.[77] Adverse reactions that go undetected often are treated with another medication to correct the drug-induced reaction.[78]

Nonetheless, data on what is reported to the FDA clearly shows that individuals 60 and older (17 percent of the population) are at far greater risk to adverse reactions than the younger population. For example, FDA data for 1985 show that of the adverse reaction reports that included the age of the victims (16,625),[79] 30 percent (5,044) involved individuals 60 and older.[80] Of the

total number of adverse reaction deaths (437) reported in 1985, 49.4 percent (216) were 60 and older. The same age group accounted for 37 percent (1,676) of the hospitalizations resulting from adverse reactions in 1985.[81] FDA data for 1986 and 1987 showed similar percentages of deaths and hospitalizations within the 60-and-older population.[82]

Researchers have estimated that adverse drug reactions are responsible for 12 to 15 percent of hospitalizations of the elderly, three or four times the rate for the younger population, and may cost more than $3 billion annually.[83-84] A recent study of 1,021 elderly medical patients with hip fractures shows "a consistent association between the current use" of sedatives, antidepressants and major tranquilizers (antipsychotics) "and an increased risk of hip fracture." [85] The study indicated that use of these drugs increases the risk of falling.[86]

Witnesses at the Aging Committee's hearing on March 25, 1988, demonstrated the sad results of inappropriate prescribing. Ann Little of Gray, TN, daughter of 77-year-old Donnis Ware, testified that her mother, who was living alone in Belington, WV, at one time was taking 17 prescription drugs along with an assortment of nonprescription, over-the-counter antacids, laxatives and pain relievers.[87] Ms. Ware's prescription drug costs for 1983 totaled $8,000.[88] After a 1-week period during which her mother was hospitalized, Ms. Little took her mother to a doctor for a followup visit. The doctor, Ms. Little testified, began writing prescriptions only 4 minutes into the visit.[89]

As the doctor was writing the seventh prescription, Ms. Little asked him what was wrong with her mother and why so many drugs were needed. Ms. Little testified:

> At this point, while still writing, the doctor informed me," just keep quiet, mind your own business, and go back to Tennessee where you belong [and] I'll take care of your mother".[90]

According to Ms. Little, the doctor threatened to call the police if she did not leave his office.[91] Two weeks later, her mother was hopsitalized because of an adverse drug reaction.[92] Ms. Little finally moved her mother from West Virginia to the Life Care Center nursing home in Erwin, TN, where most of her moth-

er's prescriptions were eliminated.[93] The Life Care Center employs a "drug holiday" program[94] for continual review of patient drug regimens in order to avoid unnecessary and potentially harmful drug reactions and interactions.[95] J.W. Colinger, Jr., M.D., medical director for the nursing home, has reduced the average number of prescription drugs per patient from 5.4 in 1984 down to 3.4 in 1988.[96]

A second witness, Ms. Wilda Henry of Golden Gate, FL, testified that her 83-year-old mother, Mrs. Cecile Howsmon, was prescribed overdoses of haloperidol by a nursing home physician and suffered damage to her liver and central nervous system.[97] Ms. Henry recalled how her mother had become uncommunicative, drooled constantly and trembled and shook uncontrollably after having received doses of as much as 20 milligrams of haloperidol in one day.[98] Ms. Henry testified that on the advice of hospital physicians, she immediately placed her mother in another nursing home where she has received appropriate care.[99]

Future Safeguards Against Adverse Drug Reactions and Waste

The Medicare Catastrophic Coverage Act of 1988 provides for development of programs to reduce the waste in unnecessary prescribing and to protect the elderly from potentially dangerous adverse drug reactions.

These programs, which will include reviews of prescriptions for individual outpatients and education outreach to physicians whose prescribing patterns may be inappropriate, are discussed in section IV of this report.

Section IV

QUALITY ASSURANCE IN PRESCRIBING

Recognizing the substantial waste and potential for serious danger associated with inappropriate prescribing, authors of the Medicare Catastrophic Coverage Act of 1988 provided for quality assurance in prescribing. Quality assurance provisions in the Act require development of two programs: a prescription drug utilization review program and an education program for physicians and pharmacists who may be inappropriately prescribing and dispensing drugs.

Drug Utilization Review Is Essential

As has been stated earlier, the consequences of inappropriate prescribing are more severe for the elderly. The creation of an effective and efficient system to promote appropriate and rational prescribing for Medicare outpatients is fully justified.

The Medicare Catastrophic Coverage Act of 1988 states in part:

> The Secretary [of the Department of Health and Human Services (DHHS)] is required to establish a utilization review program for covered outpatient drugs to identify instances of unnecessary or inappropriate prescribing or dispensing practices and to identify quality of care problems.[100]

Today's advanced computer technology will play a major role in drug utilization review with the pharmacist serving as the primary link in the program. A federally funded computer system will be installed in each participating pharmacy by January 1, 1991, when Medicare's phased-in coverage of all prescription drugs begins. The pharmacist will be responsible for entering into the computer all pertinent information on each prescription filled for a Medicare outpatient drug beneficiary.

The computer system will keep on file such information as identities of the outpatient, prescribing physician and dispensing pharmacist, prescription cost, name of drug and dosage prescribed. Several major drugstore chains have for years had computer systems with similar, and even broader, capabilities. Medicare's computer system will serve three major functions: (1) determine when a Medicare beneficiary's drug coverage deductible is satisfied, (2) bill Medicare for covered prescriptions, and (3) drug utilization review.

Congress made it clear that it wants the pharmacist to serve as the gatekeeper in drug utilization review. House and Senate conferees specifically stated that they "expect[ed] that participating pharmacists will review the medication profile of beneficiaries for potential adverse reactions before filling prescriptions." [101]

If designed properly,[102] the computer system will be able to provide the pharmacist upon request a profile or listing of all the prescription drugs being taken by an outpatient beneficiary. The ability of the pharmacist to examine the outpatient's drug profile prior to filling a prescription is critical to drug utilization review. The pharmacist may be able to prevent pain and suffering, costly hospitalizations and even deaths caused by adverse drug reactions. With the drug profile at his fingertips, the pharmacist may be able to determine:

Whether the prescription the pharmacist is about to fill has the potential for interacting with one or more other drugs being taken by the outpatient and causing an adverse reaction;

Whether the prescription the pharmacist is about to fill may reduce or increase the therapeutic effects of one or more other drugs being taken by the outpatient;

Whether the dosage of the prescription the pharmacist is about to fill is appropriate;

Whether the prescription the pharmacist is about to fill may worsen a pre-existing condition in the outpatient;

Whether the prescription the pharmacist is about to fill already has been prescribed for the outpatient by another physician; and

The identities of all physicians involved in the treatment of the outpatient so that the pharmacist may, if necessary, inform any one or all of the phy-

sicians of the potential effects of the prescription the pharmacist is about to fill.

Medicare's computer system, scheduled to be operational by January 1, 1991, also can be programmed to flash on the pharmacist's computer screen warnings of potential adverse drug interactions seconds after he or she enters a new prescription into the system.

The Act provides for a second level of protection in drug utilization review, which involves analysis by Government contractors of outpatients' drug profiles after their prescriptions have been filled and the information entered into the computer. The Secretary of the Department of Health and Human Services is required "to establish a program to identify: (i) instances and patterns of unnecessary or inappropriate prescribing or dispensing practices; (ii) instances or patterns of substandard care; and (iii) potential adverse drug reactions [that may have gone undetected by pharmacists]." [103]

Education Outreach Can Reduce Inappropriate Prescribing

The purpose of the second level of drug utilization review is to support an education program for physicians and pharmacists. Correcting inappropriate prescribing patterns among physicians can save tens, perhaps hundreds, of millions of dollars each year in drug costs, hospitalizations, and other health care expenditures.

The Medicare Catastrophic Coverage Act of 1988 requires the Secretary of the Department of Health and Human Services to establish a program to correct inappropriate prescribing and dispensing practices and patterns exhibited by physicians and pharmacists. The program "is expected to include a range of educational interventions, from written to face-to-face communications." [104]

Several States have had success with similar education outreach programs in administering their Medicare drug coverage programs. Findings of a federally funded study conducted in three States and the District of Columbia provide further evidence of the need for an education outreach program.[105] The study found that brief counseling visits of medical school-based clinical pharmacists with physicians in the survey resulted in a 14

percent decrease in inappropriate prescribing of three drug categories for Medicaid recipients.[106] Physicians, described as "highly receptive" to the counseling visits, reduced their prescribing by 31 percent.[107]

The importance of education outreach was emphasized very strongly by the Surgeon General's Workshop on Health Promotion and Aging held in Washington, DC in March 1988. Fifteen of the Workshop's 33 recommendations dealt with research and edcuation concerning needed improvements in drug prescribing for the elderly. One of those recommendations addressed the need for education as a part of drug utilization review:

> Correction of problems detected by drug utilization programs should emphasize education of professionals and not sanctions. Such efforts should be based upon current credible scientific indicators of medical practice and should focus upon direct professional and collegial contact.[108]

Section V

FDA'S ROLE IN SAFEGUARDING AGAINST ADVERSE DRUG REACTIONS

Since 1938, the U.S. Food and Drug Administration (FDA) has been responsible for ensuring the safety and effectiveness of new drugs before and after they are marketed for treating illnesses and diseases. FDA plays a vital role in safeguarding the elderly, as well as the younger population, against adverse drug reactions. Unfortunately, the FDA's regulatory process suffers from longstanding deficiencies concerning safeguards for the elderly, in both the approval and post-marketing surveillance of new drugs.

Deficiencies in the New Drug Approval Process

The FDA's approval process for new drugs is both lengthy and painstaking for the FDA as well as for the pharmaceutical manufacturer. Development of a new drug, through the approval process, takes from 2 to 10 years—5 years on average. The drug manufacturer must provide the FDA physicians, chemists, pharmacologists, and other scientists with voluminous reports and data on testing of the drug in animals, in healthy humans and, finally, in clinical trials with patients.

CLINICAL TRIALS

Prior to gaining FDA approval, the manufacturer tests the new drug in numerous clinical trials conducted by physicians and hospitals involving from 1,000 to several thousand patients. Many manufacturers, however, tend to not include elderly patients in their clinical trials because of their frailties and susceptibility to adverse drug reactions. Consequently, many drugs used heavily by the elderly have gone to market with little data concerning their effects on the older patient.

Scientists in academia, as well as at the FDA and the National Institute on Aging (NIA) for years have urged the FDA to publish guidelines for premarket clinical

testing of new drugs in elderly patients. However, these guidelines, which were drafted in 1983, have yet to be published.

In 1982, the Director of NIA, Robert Butler, emphasized to FDA Commissioner Arthur Hull Hayes, Jr., the need for specific guidelines for testing new drugs in the elderly.[109] In testimony before the Special Committee on Aging in 1983, Hayes said the agency was committed to publishing the guidelines, and had circulated a draft, but could not "predict when a final guideline will be completed." [110] Since 1983, the guidelines have been drafted and redrafted four times. The most current version is dated December 1986.

The FDA was invited to testify at the Aging Committee's March 25, 1988 hearing, "Adverse Drug Reactions: Are Safeguards Adequate For The Elderly." [111] The FDA had been asked to address several questions, including why the FDA has failed to finalize and publish its 5-year-old draft Guidelines For Clinical Testing Of Drugs In The Elderly.[112] The agency, however, refused to send a representative and failed to submit written testimony addressing the Committee's questions.[113] The letter of refusal came the same day that the Surgeon General's Workshop on Health Promotion and Aging released its list of 33 recommendations concerning the elderly and medications. Among them was the recommendation that:

> The FDA proceed with the final development and implementation of proposed guidelines for development of drugs for use in the elderly, especially elderly subgroups at risk; in particular, persons should not be excluded from clinical trials on the basis of age alone.[114]

Following the hearing, in a March 30, 1988, letter to Commissioner Frank Young, Senator John Melcher, Committee Chairman, and Senator John Heinz, Ranking Minority Member, requested to be informed no later than April 15, 1988, of "the exact date by which the FDA intend[ed] to finalize and publish its 5-year-old draft 'Guidelines For Clinical Testing Of Drugs In The Elderly'." On June 2, 1988, Commissioner Young responded that "the clinical/statistical guideline is essentially complete." [115] He further stated: "I have asked that the Center for Drug Evaluation and Research com-

plete action on a formally proposed guideline by the end of August 1988." [116] FDA informed Aging Committee staff in mid-September of yet another delay of "a couple more months." [117]

DRUG LABELING

In addition to determining the safety and effectiveness of a new drug, the FDA must approve the drug manufacturer's labeling. The drug label is supposed to provide physicians and pharmacists with all essential information, including how, and for what conditions, the medication should be used, dosages, and warnings of potential adverse drug reactions. Most of these labels for the thousands of drugs on the market contain specific sections pertaining to effects on infants, children and pregnancy, but few labels include such sections for use in the elderly.

Of the 25 most frequently prescribed drugs for the elderly in 1986,[118] only three have labels containing any reference to elderly patients and adverse reactions and only five contain statements concerning dosages for the elderly.[119] For example, in the 1988 edition of the Physicians' Desk Reference (PDR), a compendium of most prescription drug labels, the label for digoxin contains separate sections for use of the drug in pregnant women, nursing mothers, infants and children, but not for the elderly. Digoxin, however, is most often prescribed for the elderly. The elderly also suffer adverse reactions from this drug at a much higher rate than the young.[120]

Unfortunately, the vast majority of the more than 300,000 office-based physicians in the United States rely primarily on the PDR for prescribing purposes. Recognizing the inadequacies of many of the FDA-approved drug labels, the Surgeon General's March 1988 Workshop on Health Promotion and Aging recommended that:

> "new drug labeling include, where appropriate, directions for use in the elderly or other subgroups," and, "for existing [drug] products, label statements regarding use in the elderly be added incrementally as the label is revised." [121]

In his June 2, 1988 response to Chairman Melcher, Commissioner Young stated: "I have asked my staff to develop a proposed change in the regulations which would add a section on use in elderly patients [in drug labels]." The Commissioner, however, gave no date for completion of the new regulations.

Post-Marketing Surveillance Is Inadequate

The FDA's post-marketing surveillance system, which records and monitors adverse drug reaction reports on newly approved drugs, is essential to discovering relatively uncommon reactions that may have been missed in premarket clinical trials. The existing system, however, relies almost entirely upon voluntary reporting and most reactions, especially those suffered by the elderly, go unreported. Consequently, the system cannot determine the frequency of adverse reactions to accurately estimate potential risk.

Drug manufacturers are required by law to report adverse reactions that they become aware of. Nonetheless, there have been cases of drug manufacturers attempting to circumvent the law. For example, several officials from one company were jailed for failing to report adverse reactions caused by the blood pressure drug Selacryn.

Physicians and other health care practitioners are not required to report to anyone. According to the FDA, "the major weakness of the agency's post-marketing surveillance system" is that "fewer than 10 percent of physicians report reactions they have observed, and even these report only a fraction of what they see." [122]

FDA studies in five States showed that 45 percent of the physicians surveyed were not even aware of the voluntary reporting system, and only 40 percent knew how to use the system. FDA is attempting to improve better voluntary reporting through education.

RECOMMENDATIONS FOR THE MEDICARE BENEFICIARY

There are certain very important steps that can be taken by the Medicare beneficiary to ensure that he or she receives the full benefit of catastrophic drug insurance, and to safeguard against adverse drug reactions:

1. Consult your pharmacist about Medicare's forthcoming phase-in of outpatient drug coverage.
2. Although Medicare is supposed to keep records of your prescriptions, you should keep your own records and receipts of all prescription drug purchases each year so that you will know when you have met the deductible requirements ($600 in 1991).
3. Always inform your family doctor if you are being seen by one or more other prescribing physicians or dentists, and make all of your doctors and dentists aware of all medications you are taking—both prescription and nonprescription drugs.
4. The more prescriptions you are taking, the more chances you have for an adverse reaction and the greater the reason for you to go over your prescriptions with your doctor more frequently.
5. Question your doctor on each visit whether you can stop taking any of the prescriptions that you may have been taking for some time.
6. Should you begin to not feel well (dizziness, headaches, nausea, blurred vision, diarrhea, confusion, etc.), or suddenly contract a rash or hives soon after taking a new prescription, stop taking the medication and immediately consult with both your doctor and pharmacist.
7. Make certain to ask your doctor and pharmacist about how and when to take your medicine and for information on any side effects or reactions that you might experience from the drug.
8. Do not store old and discontinued drugs (prescription and nonprescription) in your medicine cabinet. Get rid of them as soon as the doctor tells you to discontinue the prescription.

RECOMMENDATIONS FOR HCFA AND FDA

1. The Health Care Financing Administration (HCFA) should dedicate adequate resources toward planning, development and administration of Medicare's outpatient drug benefit, which begins to phase in on January 1, 1990.

2. HCFA should to work closely with the state Medicaid programs to plan and coordinate policy and procedure concerning the new Medicare outpatient drug benefit as it affects each of the State Medicaid programs.

3. HCFA should immediately begin extensive consultations with private industry and with academicians expert in computer hardware and software systems prior to development of a computerized drug utilization review system.

4. HCFA should have extensive consultations with experts in academia and in the public and private sectors concerning education outreach for physicians and pharmacists on appropriate drug prescribing.

5. HCFA should rely upon the Office of the Surgeon General, the National Institute on Aging, the National Center for Health Services Research and Health Care Technology Assessment, and academia in the planning and conduct of research projects mandated by the Medicare Catastrophic Coverage Act of 1988.

6. HCFA should, in consultation with the FDA, determine whether FDA can make use of Medicare's computerized drug utilization review data base to improve safety of drugs in post-marketing surveillance.

7. FDA should publish as quickly as possible its proposed guidelines for clinical testing of new drugs in the elderly.

8. FDA should require drug manufacturers to include in drug labeling, where appropriate, a specific section on potential adverse reactions and dosage concerning the elderly.

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[94] The "drug holiday" program withdraws patients from taking psychotropic medications for 3 to 7 days in order to determine whether the drugs are necessary.

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